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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,485	09/19/2001	Michael A. Moskowitz	031695.0031	7759

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/955,485

Applicant(s)
Moskowitz et al.

Examiner
Phyllis G. Spivack

Art Unit
1614



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-35 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 21, 23, 24, and 28-35 is/are rejected.
- 7) ☒ Claim(s) 22 and 25-27 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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A Preliminary Amendment filed September 19, 2001, Paper No. 1 ½, is acknowledged. Claims 1-19 are canceled. New claims 20-35 are presented and represent all of the claims under consideration.

The undersigned Examiner supports the goal of the Office to advance prosecution as expediently as is reasonably possible. Cooperation is requested with respect to the timely submission of any references deemed pertinent to the present application along with Form PTO-1449.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20, 21 23, 24 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myslivecek et al., Neuroscience (abstract).

Myslivecek teaches the substantially contemporaneous administration of an NO-increasing agent, L-arginine, with a physiologically active composition comprising dopamine, in the brain.

The claims differ in that Myslivecek does not specifically recite an increase in cerebral bioavailability of the physiologically active agent dopamine. However, one skilled in the neurology art would have reasonably considered an improvement in learning and memory processing to have been the result of an increase in cerebral bioavailability of dopamine and NO.

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Such would have been obvious because Myslivecek teaches a dose dependent enhancement of learning and memory suggesting an increase in cerebral bioavailability of dopamine and NO.

Claims 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al., Proceedings of the Society for Experimental Biology and Medicine (abstract).

Werner teaches the requirement of various cofactors for the enzymes nitric oxide synthases. In order for the conversion of L-arginine to nitric oxide to take place, NADPH and tetrahydrobiopterin are required. Werner fails to recite a composition comprising an NO-increasing agent or agents and at least one physiologically active. However, intended use of a *misstake* composition confers no patentable weight to the composition claim. One skilled in the art would have been motivated to prepare a composition comprising the NO-increasing agent or agents with various other physiologically active agents in view of Werner's teaching. Such would have been obvious in the absence of evidence to the contrary because where the desirability of synthesizing nitric oxide is sought, Werner suggests the combination of L-arginine with various physiologically active cofactors.

Claim 35 is objected to under 37 CAR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Claim 35, directed to a site of action, does not further limit the subject matter of composition claims 29 or 30.

No claim is allowed.

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Any inquiry concerning this communication should be directed to Phyllis Spivack at
telephone number 703-308-4703.

November 26, 2002

Phyllis Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**